IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 01-504 (SLR)
	)	
SMITH & NEPHEW, INC.,	)	
	)	
Defendant.	)	

ARTHROCARE'S ANSWERING BRIEF IN OPPOSITION TO SMITH & NEPHEW'S RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW

MORRIS, NICHOLS, ARSHT & TUNNELL
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Attorneys for Plaintiff ArthroCare Corporation

OF COUNSEL:

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
Silicon Valley Office
201 Redwood Shores Parkway
Redwood Shores, CA 94065-1175
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

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NATURE AND STAGE OF THE PROCEEDING

Two years ago, on July 25, 2001, ArthroCare Corporation ("ArthroCare") filed this action alleging infringement of United States Patent Nos. 5,697,536 ("the '536 patent"), 5,697,882 ("the '882 patent"), and 6,224,592 B1 ("the '592 patent"). Defendant Smith & Nephew, Inc. ("Smith & Nephew") asserted defenses of non-infringement and invalidity as to all three patents.

Trial commenced on April 30, 2003. Although Smith & Nephew referred to Rule 50 motions several times during the course of the trial, it never made a Rule 50(a) motion on the issue of invalidity. On May 7, 2003, counsel for Smith & Nephew said that "to the extent that was the close of plaintiff's evidence, we'd move under Rule 50." (Tr. 1161). Smith & Nephew set forth no grounds for the motion and, because patent validity was not part of ArthroCare's case, Smith & Nephew's motion could not have related to issues of validity. On the last day for the presentation of evidence, May 9, 2003, counsel for Smith & Nephew said it was "renew[ing]" the Rule 50 motion it had made on May 7. (Tr. 1549). Smith & Nephew also filed a written Rule 50(a) motion for judgment as a matter of law ("JMOL") that was expressly directed *only* to issues of infringement. (D.I. 400 at 1 n.1). Smith & Nephew verbally "renewed" its Rule 50(a) motion on May 12, 2003, after the close of the evidence, and again did not mention invalidity. (Tr. 1700).

On May 12, 2003, the jury returned a verdict in favor of ArthroCare, finding that all of the asserted claims of the '536, '882, and '592 patents were infringed and not invalid. (D.I. 405). In reaching its verdict, the jury answered all 107 questions in favor of ArthroCare. On June 20, 2003, the Court entered final judgment based on the jury's verdict. (D.I. 452).

Smith & Nephew filed its Rule 50(b) motion for JMOL on June 30, 2003. (D.I. 458). As it did when it moved for summary judgment, Smith & Nephew has taken a "shotgun" approach, arguing that the jury was wrong about every single issue it considered, as if the jury was

incapable of understanding any issue in the case. Smith & Nephew even argues that the jury was wrong about issues that were not submitted to it, including infringement under the doctrine of equivalents, direct infringement of the '592 and '882 patents, and infringement of claim 54 of the '882 patent by Smith & Nephew's "non-suction" Saphyre probes.

SUMMARY OF ARGUMENT

Smith & Nephew's motion should be denied for at least the following reasons:

1. The jury's verdict of infringement of the '536 patent is supported by substantial evidence that the accused products are part of an "electrosurgical system" which includes an "electrically conducting fluid supply." It was undisputed at trial that Smith & Nephew's accused products will not work unless the electrodes are immersed in electrically conducting fluid because the electrically conducting fluid completes a circuit between the generator and the electrodes. There also was substantial evidence that, in arthroscopic surgeries performed with the accused products, electrically conducting fluid was, and indeed must be, directed to the target site from a fluid supply, such as an IV bag or special pump. Contrary to Smith & Nephew's suggestion, there is no requirement that the electrically conducting fluid be delivered to the target site by the probe, only that the probe and the electrically conducting fluid supply form part of a "unitary whole."

2. There is substantial evidence to support the jury's verdict of infringement of the '592 patent. That evidence included the testimony of Smith & Nephew's own witnesses, such as Warren Heim and expert witness Dr. Michael Choti, that when the active electrode is positioned near the target site and energy is applied, there are times when the return electrode is not in contact with the patient's tissue. Smith & Nephew's videotapes of the products in use clearly showed that the return electrode was not contacting tissue at times when energy was applied. As the Court's jury instructions stated, there is "no time limitation" during which the return electrode

must not contact the patient's tissue in order for the asserted claims of the '592 patent to be infringed.

3. Smith & Nephew did not dispute that it infringes the corrected claims of the '882 patent if the certificate of correction is valid, and it failed to carry its burden of proving by clear and convincing evidence that the certificate of correction is invalid. Smith & Nephew *put on no evidence* that one of ordinary skill in the art would not have recognized the error in the claim or how it should be corrected, based on a review of the patent and the prosecution history. Because a certificate of correction is presumed valid, and because it was Smith & Nephew's burden to prove invalidity by clear and convincing evidence, there is nothing to suggest that no reasonable jury could have reached the verdict the jury reached in this case.

4. The jury's verdict of contributory infringement is supported by substantial evidence, including the undisputed evidence that Smith & Nephew's products are designed only to be used with electrically conducting fluid and will not work without it. The jury's verdict also is supported by the testimony of Smith & Nephew witnesses Kate Knudsen and Warren Heim, both of whom admitted that they analyzed ArthroCare's patents and patented products in designing Smith & Nephew's products. The evidence further showed that Smith & Nephew designed the return electrode of each device to be positioned away from the active electrode, which reduces tissue contact, and that the accused products were designed to work without the return electrode contacting tissue. Despite this evidence, Smith & Nephew argues that no reasonable jury could have reached the verdict the jury reached in this case because the evidence that the products are used in arthroscopic surgery was "misleading." The logic of this argument is completely backwards, however. The fact that Smith & Nephew's products are designed for use in arthroscopic surgery is highly relevant evidence of contributory infringement, because electrically conducting fluid (one of the claim limitations) is conventionally used in arthroscopic surgery, as Smith & Nephew's witnesses admitted.

5. There also was substantial evidence to support the jury's verdict that Smith & Nephew induces infringement of the patents-in-suit. In addition to showing that Smith & Nephew directs its customers to use its products in an infringing way, the evidence also showed that Smith & Nephew knew about and examined ArthroCare's patents and patented products in designing the infringing products. The evidence showed that Smith & Nephew instructed its customers to use the accused products only in the presence of electrically conducting fluid, such as saline. Smith & Nephew's witnesses also confirmed that Smith & Nephew intended that the return electrode of the accused products not contact patient tissue when in use. ArthroCare also showed that Smith & Nephew designed all three of its accused products so that the return electrode would not contact the tissue by spacing the return electrode proximally from, or on a different plane than, the active electrode. This design induces infringement because, when the active electrode is positioned close to, or in contact with, the target tissue and high-frequency energy is applied, the return electrode is positioned so that there are times when it is spaced away from the tissue.

6. Smith & Nephew's invalidity allegations must be rejected because Smith & Nephew did not preserve the issue by making a Rule 50(a) motion on invalidity before the case was submitted to the jury. Smith & Nephew's failure to preserve the issue is fatal to its "renewed" Rule 50(b) motion insofar as it relates to invalidity.

7. Even if Smith & Nephew had preserved the issue, there was substantial evidence from which the jury could conclude that Smith & Nephew failed to establish invalidity by clear and convincing evidence. Both of Smith & Nephew's experts on invalidity, Dr. Taylor and Dr. Manwaring, made critical admissions about the prior art which showed that claim limitations were missing from each asserted reference. Moreover, because all of the references Smith & Nephew asserted had been disclosed by ArthroCare to the Patent Office when the patents-in-suit were originally prosecuted or during the '536 Reexamination, Smith & Nephew faced a "more difficult" task in trying to meet its burden of proving invalidity by clear and convincing evidence.

STATEMENT OF FACTS

The relevant facts are set forth in the Argument sections, as appropriate.

ARGUMENT

I. THERE WAS SUBSTANTIAL EVIDENCE FROM WHICH A REASONABLE JURY COULD CONCLUDE THAT SMITH & NEPHEW INFRINGED THE PATENTS-IN-SUIT.

A. The Legal Standard For Judgment As A Matter Of Law.

Smith & Nephew is not entitled to JMOL under Rule 50(b) unless it can show that "there is no legally sufficient evidentiary basis for a reasonable jury to find" in ArthroCare's favor. A Rule 50(b) motion may be granted "only if, as a matter of law, the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief." *Trabal v. Wells Fargo Armored Serv. Corp.*, 269 F.3d 243, 249 (3d Cir. 2001). In deciding a Rule 50(b) motion, the Court must review the evidence in a "light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). Thus, for Smith & Nephew to prevail on its JMOL motion, it must show that "the evidence and the justifiable inferences therefrom do not afford any rational basis for the verdict." *Bates v. Board of Educ.*, 2000 WL 376405, at *1 (D. Del., Mar. 31, 2001).

A jury's verdict may not be set aside under Rule 50(b) merely because the Court disagrees with the jury's decisions as to the weight or credibility of the testimony presented at trial. *Amsted Indus., Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 183 (Fed. Cir. 1994)) ("It is within the province of the jury to determine the credibility of a witness and the weight to be given his testimony; the jury is not required to accept testimony as true, even if it is uncontradicted."). Nor is JMOL proper simply because the jury did not believe the evidence of the party that lost at trial. *Comark Communs. v. Harris Corp.*, 156 F.3d 1182, 1192 (Fed. Cir. 1998) ("Simply because evidence is offered at trial does not mean that the court must assume the jury believed the

evidence or gave it the same weight as does the profferor of such evidence."). The Court may not substitute its own judgment for that of the jury about the weight of the evidence, the credibility of witnesses, or legitimate inferences that can be drawn from that evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151 (2000) ("although the Court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe.").

In sum, Smith & Nephew cannot prevail on its motion if "a reasonable jury, given the facts before it, could have arrived at the conclusion" of the jury in this case. *TA Instrs., Inc. v. Perkin-Elmer Corp.*, No. 1998 WL 883446, at *2 (D. Del. Dec. 7, 1998). Thus, motions such as Smith & Nephew's "should be granted sparingly." *Lightning Lube*, 4 F.3d at 1166.

B. Smith & Nephew Cannot Seek JMOL On Issues That Were Not Submitted To The Jury.

Smith & Nephew argues that, under Rule 50(b), it is entitled to JMOL on the issues of (1) infringement under the doctrine of equivalents, (2) infringement of claim 54 of the '882 patent by the non-suction models of the Saphyre probe, and (3) direct infringement of the '592 and '882 patents. (D.I. 459 at 5, 6, and 19.). Smith & Nephew does not cite, nor is ArthroCare aware of, any support for this request. Rule 50(b), and the case law applying it (including that discussed above), plainly contemplate an adverse jury verdict as a predicate for a motion for JMOL. *Goodman v. Pennsylvania Turnpike Com'n, 293 F.3d 655, 664* (3d Cir. 2002)("key" to Rule 50 motion is "evidentiary basis for the verdict"); *TI Group Automotive Sys.(North America), Inc. v. VDO North America, L.L.C, 2003 WL 21302951, at *1* (D.Del. June 6, 2003) (analysis of a renewed motion for JMOL following a jury trial required analysis of "jury's verdict" and "jury's findings, presumed or express".) Here, none of the issues Smith & Nephew raises was presented to the jury, none of them was mentioned in closing arguments, and neither the jury instructions nor the verdict form refers to them. As such, Smith & Nephew is not entitled to JMOL on any of these issues.

Moreover, each of the three issues is independently unsuitable for resolution on a motion for JMOL. With respect to the doctrine of equivalents, there is no need for the Court to reach this issue on Smith & Nephew's motion because the jury found literal infringement. *Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001) (finding that because "substantial evidence supports a finding of literal infringement, it is not necessary for us to address the issue of infringement under the doctrine of equivalents."); *Tate Access Floors, Inc. v. Maxcess Techs.*, 222 F.3d 958, 970 (Fed. Cir. 2000) ("Based on [a conclusion of literal infringement], we need not reach the parties' arguments with respect to infringement under the doctrine of equivalents."). As for infringement of the suction claim of the '882 patent, Smith & Nephew acknowledged at trial that claim 54 was not asserted against the non-suction Saphyre probes. (Tr. 1493-94.) As the evolution of the verdict form made clear, Smith & Nephew originally had sought to have the jury render a verdict on Claim 54 for both the Saphyre with suction and without suction, but agreed to change the verdict form so that it only asked about the Saphyre without suction. (*Id.*). With respect to whether Smith & Nephew directly infringes the '882 and '592 patents, ArthroCare never argued at trial that Smith & Nephew directly infringed these two patents or requested a verdict from the jury.

C. The Great Weight Of The Evidence Supports The Jury's Verdict That Smith & Nephew Infringes The '536 Patent.

1. The Evidence At Trial Conclusively Demonstrated That The Accused Devices Are Used In An "Electrosurgical System" Which Includes An "Electrically Conducting Fluid Supply."

Smith & Nephew's argument that no reasonable jury could find that it infringes the '536 patent rests on a false premise: that the Court's construction of the term "system" to mean "an assemblage or combination of things or parts forming a unitary whole" (D.I. 353 at 5), requires that the electrically conducting fluid be delivered to the target site through a fluid path in the

probe. (D.I. 459 at 9). There is nothing in the Court's claim construction, however, that requires the probe to deliver the electrically conducting fluid to the target site.[1] In reaching its construction, the Court rejected Smith & Nephew's proposed construction of this phrase, which would have required that the fluid supply be "in fluid communication with the probe, directing electrically conducting fluid to the electrodes at the end of the probe." (D.I. 270 at 22). Smith & Nephew's present argument, that there can be no infringement because there is no "fluid communication," is simply an improper attempt to reargue this rejected claim construction.

There was substantial evidence at trial that the accused products and the electrically conducting fluid supply used with them meet the "electrosurgical system" limitation of claim 45 as construed by the Court.[2] As Dr. Goldberg testified, when electrosurgical devices like the accused devices are in operation, an electrical circuit is created between the active and return electrodes through the electrically conducting fluid. (Tr. 384, 398). He also testified that the accused devices will only work in electrically conducting fluid. (Tr. 398-99, 405, 412). Smith & Nephew's expert, Dr. Taylor, concurred, testifying that the accused devices require, and will not work without, electrically conducting fluid. (Tr. 1453-54). The jury was free to conclude that this constitutes a system, just as the collection of planets around the sun is commonly referred to as the "solar system," even though the planets are not physically connected to one another or to the sun, as Dr. Goldberg explained. (Tr. 383).

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[1] The fact that the phrase "electrosurgical system" in claim 45 does not require that the probe deliver the fluid to the target site also is shown by comparing claim 1 and claim 45 of the '536 patent. Claim 1 calls for a "fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal." (JTX 1). Had the inventors intended that claim 45 require that the fluid travels through a "fluid path" down the probe, they could have used the same or similar language as they did in claim 1. That such language is entirely absent from claim 45 demonstrates that the probe need not deliver the fluid to fall within claim 45.

[2] Asserted claims 46, 47, and 56 depend from unasserted claim 45.

Dr. Taylor admitted that a probe is not required to deliver fluid in order for the fluid supply and the probe to be considered an "electrosurgical system." (Tr. 1413-16). Dr. Taylor testified about an alleged prior art reference called the Slager reference. (Tr. 1413). The Slager reference described a test in which an electrode was placed in a dish with saline. (Tr. 1413-14). There was no mention in the article of how the electrically conducting fluid was directed to the target site, much less whether the electrically conducting fluid was delivered through the probe. (Tr. 1415). Yet Dr. Taylor testified that even though the fluid was not delivered through the probe, the components described in the Slager reference nonetheless comprised an electrosurgical system:

> Q: What I am asking, sir, is in this experiment, where you have a dish, you have some tissue in the dish, you have saline that has been put into the dish, you bring an electrode in contact with the tissue, and you apply energy in a generator, that is describing an electrosurgical system. True?
>
> A: Yes.
>
> Q: And it's describing an electrosurgical system even though we don't have any idea how the fluid got into the dish; correct?
>
> A: That's right.
>
> Q: And it's an electrosurgical system even though the fluid didn't come in through the electrode that is described here in Slager; correct?
>
> A: Yes.

(Tr. 1414). Given this testimony, a reasonable jury could conclude that the accused products meet the "electrosurgical system" limitation of claim 45.

In addition, there was substantial evidence that Smith & Nephew itself considered the accused products and the fluid supply used with them to be part of an electrosurgical system, even though the fluid is delivered to the target site by a device other than the probe. For example, the Instructions For Use ("IFU") for the ElectroBlade describes a "Recommended System Configuration" which includes an InteliJet (a pump manufactured by Smith & Nephew) for

providing electrically conducting fluid to the target site.[3] (PX 189 at 3). The InteliJet delivers the fluid directly to the tissue site through a portal as opposed to through the ElectroBlade itself. (Tr. 789-90). Smith & Nephew nonetheless describes the InteliJet and the ElectroBlade as being part of the same "Recommended System Configuration" in its IFU. (PX 189 at 3).

At trial, Smith & Nephew argued that the ElectroBlade IFU did not describe the ElectroBlade and the InteliJet as part of a "system" because the word "system" was allegedly used as an adjective, not a noun. (Tr. 1039). This is plainly incorrect. The IFU uses the word "system" repeatedly as a noun: "the system should be tested," "the configured system exceeds," "retest the system," "this system must be certified," and "this system." (PX 189 at 3). The jury was reasonably entitled to interpret the IFU as an admission that a "system" included a fluid supply and a probe that were not physically connected to each other.

2. The Evidence Demonstrated That The Infringing Products Are Part Of An Electrosurgical System Which Includes A Fluid Supply "For Directing Fluid To The Target Site."

ArthroCare also introduced substantial evidence from which a reasonable jury could conclude that the infringing products are part of a system with a fluid supply "for directing fluid to the target site" as required by the asserted claims of the '536 patent.[4] Dr. Goldberg, Dr. Choti, and Mr. Sparks all testified that in arthroscopic surgery, the entire joint space must be filled with an electrically conducting fluid in order to allow the surgeon to visualize and operate on target sites in the joint. (Tr. 399, 727, 848 (according to Dr. Choti, "one purpose of the fluid in the joint

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[3] Smith & Nephew's attempts to diminish the significance of this document by claiming that the system recommended in the IFU was only recommended for Europe should be rejected. (D.I. 459 at 9 n.1). The IFU states that "this recommended system configuration complies" with European standards, not that the recommendation only applies to systems used in Europe. (PX 189 at 3).

[4] Smith & Nephew never argued at trial that the accused products do not meet the "directing fluid to the target site" limitation.

space is to distend it to allow as much space as possible to work with instruments"). As Dr. Goldberg further testified, all of the surfaces of the joint space are in contact with the electrically conducting fluid as a result of the joint space being filled with fluid. (Tr. 429-30). In this way, electrically conducting fluid is delivered to the target site during arthroscopic surgery. (*Id.*).

Similarly, Smith & Nephew's own documents introduced into evidence show that the electrically conducting fluid is directed to the target site. Smith & Nephew's "Supplemental Clinical Training Checklist" for the ElectroBlade required surgeons to confirm that they understood that the active and return electrodes must be "completely surrounded by irrigant fluid" before the application of RF energy. (PX 197 at SN46968). The Control RF IFU instructs doctors to "ensure that the probe tip is completely surrounded by conductive irrigant solution during use." (PX 205). As for the Saphyre, the Saphyre Sales Guide states that "a conductive irrigation solution, such as Lactated Ringers or sterile saline is required for arthroscopic surgical procedures." (PX 390 at 12). The jury was also shown multiple video clips made by Smith & Nephew and Dr. Choti which showed the accused devices in operation. (PX 105, DTX 315, DTX 316, DTX 897)). These clips all showed fluid that had been delivered to the target site, as the tissue was shown completely submerged under saline. (*Id.*, Tr. 724-25). According to Dr. Choti, his video clips depicted the devices in use during what he considered a "normal procedure." (Tr. 724). This was substantial evidence that the electrically conducting fluid is directed to the target site.

In essence, Smith & Nephew is seeking to re-litigate its rejected claim construction. In its claim construction brief, Smith & Nephew argued that the phrase "directing electrically conducting fluid to the target site" should be construed to mean that the electrically conducting fluid "is caused to flow directly to the tissue being operated on in the patient's body." (D.I. 246 at 31). The Court rejected this argument, finding instead, as ArthroCare had urged it to, that no construction was necessary and that "the phrase shall be construed consistently with its ordinary

meaning." (D.I. 353 at 3). The jury was free to find that the ordinary meaning of "directing fluid to the target site" covers the use of a catheter that floods the target tissue with fluid.

D. There Was Substantial Evidence From Which A Reasonable Jury Could Conclude That Smith & Nephew Infringes The '592 Patent.

1. The Jury's Verdict That The Accused Products Meet The "Not In Contact/Spaced Away" Limitations Of The '592 Patent Is Supported By Substantial Evidence.

In disputing the jury's verdict that it infringes the '592 patent, Smith & Nephew attempts to reargue the claim construction arguments it made, and lost, before trial. In its claim construction brief, Smith & Nephew argued that the "not in contact/spaced away" limitations of the '592 patent "require that the return electrode be kept away from, and not [be] allowed to touch any portion of the body structure during surgery." (D.I. 246 at 26). The Court rejected this position, and construed claims 1 and 23 of the '592 patent to require only that "the return electrode is not to contact the body structure at all during the performance of the claimed method." (D.I. 353 at 2). The Court also ruled that "[t]he claimed method does not contain any time limitations." (D.I. 354 at 7). Thus, under the Court's construction, infringement occurs if all of the claimed steps occur even for a short time.

As Dr. Goldberg's testimony made clear, and as ArthroCare properly argued to the jury, the use of the accused products infringes because there are times when all of the other limitations of the claims are being performed and the return electrode is not in contact with tissue. (Tr. 421-22, 424-25, 426-27). This occurs because, among other things, the accused products were designed with the return electrode spaced back from, and in the case of the Saphyre and Control RF, on a different plane than, the active electrode. (Tr. 397, 424, 427).

At trial, Smith & Nephew effectively admitted that the use of its products meets the "not in contact/spaced away" limitations. One of Smith & Nephew's experts, Dr. Choti, readily

conceded that when the active electrode is positioned near the target site and energy is being applied, there are times when the return electrode of each accused product is not in contact with tissue. (Tr. 743-44). Dr. Choti and Smith & Nephew also recorded video clips of his testing of the accused products in operation which showed the devices in use with the return electrode not in contact with tissue while all of the other limitations were being met. (PX 105). According to Dr. Choti, this testing was intended to show how the devices would work during a normal procedure. (Tr. 724). Ms. Drucker, the ElectroBlade project manager, and Ms. Knudsen, the Saphyre project manager, both acknowledged that these clips demonstrated that there were times when the return electrodes of the ElectroBlade and the Saphyre were not in contact with tissue when energy was being applied. (Tr. 985, 1036). Warren Heim, Smith & Nephew's consultant, testified that the Control RF and ElectroBlade were designed so that the return electrode would not be in contact with the tissue when the devices were in use. (Tr. 957-58, 581-82). Likewise, Joan McCreary, the Saphyre marketing manager, and Dr. Choti testified that it is not necessary for the return electrode of the Saphyre to be in contact with tissue for it to work. (Tr. 555, 725). This is substantial evidence in support of the jury's verdict.

Smith & Nephew's own documents also demonstrate that there are times when all of the other limitations of claims 1 and 23 are met and the return electrode is not in contact with tissue. For example, the Saphyre Sales Guide warns that "care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." (PX 390 at 41). A Smith & Nephew document, entitled "Competitive Selling ArthroCare," teaches that the active electrode of the Saphyre should be held level against the tissue to be ablated. (PX324 at ORA65090) ("During use, keep the electrode level with the target tissue for optimal evacuation of bubbles."). Given the geometry of the probe, the return electrode will not contact the tissue when Smith & Nephew's instructions are followed because the return electrode is spaced back from, and on a different plane than, the active electrode.

With respect to the ElectroBlade, Smith & Nephew's Sales Training CD instructs users to "ensure that the entire tip including the return electrode is immersed in saline," to "[p]resent" the active electrode (not the return electrode) to the tissue, and "to use suction to pull bleeding tissue to the blade for coagulation." (PX 199 at 7, 11). Because the return electrode is located distally from and behind the blade, following these instructions will result in the return electrode contacting fluid, not tissue.

For the Control RF, the IFU tells doctors to be sure that the active and return electrodes are "completely surrounded" by electrically conducting fluid during use. (PX 205). Due to the spacing of the return electrode proximally from, and on a different plane than, the active electrode, the use of the Control RF according to these instructions will result in times when there is no tissue contact. (Tr. 424). All of this is substantial evidence from which a reasonable jury could conclude that the use of the accused products meet the "not in contact/spaced away" limitations.

2. ArthroCare's Evidence With Respect To The "Not In Contact/Spaced Away" Limitations Was Not Improper.

Smith & Nephew does not dispute that there are times when the return electrode is not in contact with tissue and all of the other limitations are met. (D.I. 459 at 12). Instead, it raises a litany of alleged improprieties with the overwhelming evidence ArthroCare presented on infringement.

Foremost among Smith & Nephew's complaints is that ArthroCare ignored the Court's claim construction and instead used a "rejected" claim construction to demonstrate infringement of the "not in contact/spaced away" limitations.[5] (D.I. 459 at 10-11). Smith &

[5] ArthroCare's evidence cannot be based on a "previously rejected" claim construction because ArthroCare did not propose a claim construction for these limitations. Indeed, ArthroCare took the position that the meaning of the "not in contact" limitations was clear and that no construction was needed. (D.I. 270 at 49).

Nephew is wrong. The Court's construction requires only that "the return electrode is not to contact the body structure at all during the performance of the claimed method." (D.I. 353 at 2). As the Court made clear in ruling on summary judgment, "the claimed method does not contain any time limitations." (D.I. 352 at 7). Thus, the claimed method is performed when the active and return electrodes are in the presence of electrically conducting fluid, energy is applied, and the return electrode is not in contact with tissue. There can be no dispute that ArthroCare presented substantial evidence, discussed above, that there are times when these limitations are met by the accused devices.

It is Smith & Nephew that relies on a rejected claim construction. The Court declined to adopt Smith & Nephew's proposed construction that the return electrode must not contact tissue at any time during the entire surgery. (D.I. 353 at 2, D.I. 246 at 26). In its summary judgment Opinion, the Court stated that "defendant does not dispute that, at times during surgery, the return electrode of the accused product is not in contact with the body structure and each of the three steps of the claimed method are performed. The Court, therefore, finds that the use of the Saphyre product literally infringes claim 1 of the '592 patent." (D.I. 352 at 7). The Court instructed the jury that "[t]he claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed." (Tr. 1718). The jury was also instructed that infringement occurs so long as the accused devices "operate in a way that meets each and every step of the method described in the claim some of the time." (Tr. 1716). Smith & Nephew now pretends that the claim construction was something different than it was because that is the only way it can argue that it does not infringe.

Smith & Nephew also argues that ArthroCare attempted to "mislead" the jury when it showed still images from video clips depicting the accused devices performing the claimed methods. (D.I. 459 at 12 n.8). This argument must fail. Smith & Nephew did not object at trial

to any of the uses of the still images about which it now complains.[6] Moreover, Smith & Nephew and ArthroCare proffered, and played for the jury, longer video clips from which the still images were taken. Like the longer video clips themselves, the still images simply showed that the active electrode was near the tissue, that both the active and return electrodes were submerged in electrically conducting fluid, and that the return electrode was not in contact with the tissue while energy was being applied.

Contrary to Smith & Nephew's assertions, ArthroCare did not argue that the return electrode must always be in contact with the tissue in order not to infringe the '592 patent. (D.I. 459 at 10-11). Rather, Dr. Goldberg and counsel for ArthroCare made clear that literal infringement occurs when the return electrode is not in contact with the tissue and all of the other limitations are met. Indeed, ArthroCare's counsel acknowledged that there was no literal infringement at those times when the return electrode was in contact with tissue. (Tr. 1580-81). ArthroCare's evidence and arguments squarely met the Court's claim construction and were not misleading.

3. It Was Not Unreasonable For The Jury To Reject Smith & Nephew's Argument That Occasional Contact By The Return Electrode Negates Other Instances Of Infringement.

Smith & Nephew's contention that the use of its products does not infringe because the return electrode occasionally contacts the tissue has no merit. (D.I. 459 at 13). Smith & Nephew's argument seems to suggest that if a surgeon is performing all of the steps of the claimed methods for three seconds and then, in the fourth second, the return electrode contacts the tissue, there was no infringement in the first three seconds and there could not be any infringement thereafter.

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[6] ArthroCare was precluded from using still images from these video clips with Dr. Goldberg as part of his direct testimony. Thus, ArthroCare was forced to rely on the video clips that Smith & Nephew used to examine witnesses, which is precisely what it did.

Smith & Nephew's argument is incorrect because it runs afoul of the Court's jury instruction on the "not in contact/spaced away" limitation, which stated that "there is no time limitation on this claim term," and the Court's instruction on imperfect infringement, which stated that infringement occurs so long as the accused devices "operate in a way that meets each and every step of the method described in the claim some of the time." Using the example above, and in light of these instructions, the jury reasonably concluded that return electrode contact in the fourth second of a procedure does not negate infringement during the first three seconds.

4. ArthroCare Presented Substantial Evidence That Doctors Do Not Touch The Return Electrode To Tissue During Use Of The Accused Products.

Contrary to Smith & Nephew's assertions, ArthroCare presented substantial evidence that the accused devices were used in an infringing way. There was no requirement that ArthroCare present direct evidence that doctors do not touch the return electrode to tissue. (D.I. 459 at 13). As the jury was instructed, circumstantial evidence is no less persuasive than direct evidence. (Tr. 1706).

There was ample circumstantial evidence from which the jury could conclude that a doctor used the accused devices for some period of time without the return electrode contacting tissue. This can be inferred from the design of the accused products themselves. (PX 113A, PX 113B, PX 544, PX 732). For example, the evidence showed that the return electrodes are spaced away from, and on a different plane than, the active electrode, and therefore that the accused products were designed so that the return electrode would not contact tissue. (Tr. 397). Warren Heim also admitted that the return electrodes on both the Control RF and the ElectroBlade were designed not to contact tissue. (Tr. 581-82). In addition, the video clips recorded by Smith & Nephew's expert Dr. Choti and played to the jury (PX 105) showed that the return electrode was not in contact with tissue when the devices are in use during a "normal procedure." (Tr. 724).

All of this supports the reasonable inference that doctors used the devices for some period of time without the return electrode contacting tissue.

The jury also could have concluded that doctors used the probes for some period of time without the return electrode contacting tissue from the evidence that Smith & Nephew instructed users not to contact the return electrode with tissue, including its own IFUs, Sales Guides, and Sales Training CD for the accused products. The jury reasonably could have inferred that doctors followed these instructions.

E. A Reasonable Jury Could Conclude That Smith & Nephew Had Not Met Its Burden Of Proving By Clear And Convincing Evidence That The Certificate Of Correction For The '882 Patent Is Invalid.

1. Smith & Nephew Put On No Evidence That The Certificate Of Correction Was Invalid.

At trial, Smith & Nephew did not contest that its accused products infringe the asserted claims of the '882 patent as corrected by the certificate of correction. Smith & Nephew's entire noninfringement case was based on its argument that the certificate of correction is invalid. To prove that the certificate of correction is invalid, however, Smith & Nephew had to show by clear and convincing evidence that one skilled in the art would not recognize the error in the originally issued claim or know how to fix it in light of the patent and the prosecution history. (Tr. 1733-34); *Superior Fireplace Co. v. The Majestic Prods. Co.*, 270 F.3d 1358, 1370 (Fed. Cir. 2001).

Despite its burden, Smith & Nephew presented no expert testimony about what one of ordinary skill in the art would have understood about the errors in claim 1. In the face of Smith & Nephew's failure to offer any evidence, the jury was entitled to conclude that Smith & Nephew had not met its burden.

In addition, there was substantial evidence that the certificate of correction was valid. First, the evidence at trial showed that the error was the result of a typographical or clerical error in a March 25, 1997 amendment, namely the failure to change the phrase "active electrode" to

"electrode terminal" in two of the 19 places where it appeared in the claims. Mr. Raffle, who drafted the March 25, 1997 amendment, explained that he had "wanted to make a global amendment" to change "active electrode" to "electrode terminal" every time it appeared in the claims. (Tr. 1524-26). From this testimony, the jury was free to conclude that a person of ordinary skill would have seen that the change had been made 17 out of 19 times and, in the two places that it was not made, the phrase "active electrode" should have been changed to "electrode terminal."

Second, as Mr. Raffle testified, the phrase "the active electrode" technically lacked an antecedent basis in uncorrected claim 1, because the precise words – "an active electrode" – had not been used earlier in the claims. (Tr. 1515-16). The Court, however, construed the phrase "electrode terminal" to mean "one or more active electrodes." (Tr. 1719). From this, the jury reasonably could have inferred that a person of ordinary skill looking at the uncorrected claim would have realized that the reference to "the active electrode" after the reference to "an electrode terminal" was a typographical or clerical error, that the drafter had intended to refer to the same electrode, and that the phrase "the active electrode" should have been "the electrode terminal."

Given all of this, the jury could reasonably conclude that a person of ordinary skill would know what the error was (not changing "active electrode" to "electrode terminal" all 19 times) and how to fix it (change "active electrode" to "electrode terminal" as Mr. Raffle had done 17 other times).

Despite this, and with no evidence to support its invalidity argument, Smith & Nephew argues that no reasonable jury could have rejected the inferences urged by its attorneys. Those inferences, however, were reasonably rejected by the jury.

First, Smith & Nephew argues that Mr. Raffle's failure to change "active electrode" to "electrode terminal" in one place in claim 26 with the December 17, 1997 request for certificate of correction supports the inference that the error in claim 1 and its correction were not clear.

(D.I. 459 at 18-19). The request for certificate of correction, however, is of no significance to whether the error in the uncorrected language of claim 1 and its correction would have been clear to one of ordinary skill. The fact that there may have been an error in the request for certificate of correction does not establish that the error in claim 1 was not clear; it only establishes an error in the request for certificate of correction.

Second, Smith & Nephew argues that Mr. Raffle's failure to change "active electrode" to "electrode terminal" in one place in each of claims 1 and 26 means that the error in claim 1 was not "manifest." (D.I. 459 at 15-16). This argument makes no sense. Anyone reviewing the file history would see immediately that the drafter of the March 25, 1997 amendment had intended to change "active electrode" to "electrode terminal" every place it appeared, and that nowhere in the amendment was the phrase "electrode terminal" changed to "active electrode." Thus, the fact that an error was made as to claim 26 as well as claim 1 shows only that an error was made in both claims, not that the error in claim 1 was not "manifest."

Third, Smith & Nephew argues that Mr. Raffle was motivated to amend claim 1 in order to sue Ethicon. (D.I. 459 at 19). There is no basis for this argument. If this were correct, Mr. Raffle would have been motivated to amend claim 26 as well, which contained the same errors as claim 1. But Mr. Raffle did not amend claim 26.

Smith & Nephew's final argument on the '882 patent is that ArthroCare did not object to the examiner's inclusion of the uncorrected claim language in his statement of reasons for allowance. (D.I. 459 at 17-18). This proves nothing, however, other than that the examiner repeated the typographical or clerical error in the statement of reasons for allowance. Moreover, there was no reason for ArthroCare to respond to the statement because the claims were allowed. This is much different than the situation in *Superior Fireplace* where the patentee had engaged in

a substantial, back-and-forth exchange with the examiner over patentability. *Superior Fireplace*, 270 F.3d at 1370.[7]

F. There Was Substantial Evidence From Which A Reasonable Jury Could Find Contributory Infringement.

1. The Evidence Showed That The Accused Products Are Specially Designed To Infringe.

There was strong evidence that the accused products were specially designed to infringe. Both Kate Knudsen and Warren Heim testified that they were aware of ArthroCare's patents covering bipolar electrosurgical devices long before the design of the infringing products was complete, and that Mr. Heim wrote a report to Smith & Nephew analyzing the patents. (Tr. 936-37, 991, PX 735 at 23-24). Smith & Nephew also tested and evaluated ArthroCare's patented products while designing its own products. (Tr. 377-78, 586-90, 593-94, 951, PX 240). Substantial evidence showed not only that the accused products cannot work without electrically conducting fluid, but also that they are designed so that the return electrode will not contact tissue. (Tr. 415-19, 397-98, 405, 412, 949). From this, it was reasonable for the jury to conclude that the accused products were specially designed to infringe.

Smith & Nephew's argument that it was "facially misleading and prejudicial" for ArthroCare to present evidence showing that the accused devices are used in arthroscopic surgery is absurd. (D.I. 459 at 20). It was undisputed at trial that Smith & Nephew encourages doctors to use its accused products in arthroscopic surgery and that the accused products are *contraindicated* for any other procedure. (Tr. 499-500). The witnesses who testified on this point were unanimous that arthroscopic surgery is performed by flooding the joint space with an electrically

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[7] Smith & Nephew's citation to *Elkay Mfg. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999), *cert. denied*, 529 U.S. 1066 (2000), also is inapposite because that case dealt with the effect on claim construction of the applicant's silence in the face of a statement by the examiner, not whether an error in a patent claim was clear.

conducting fluid and performing the surgery with the probe and target tissue immersed in the fluid. (Tr. 483-96, 548-53, 847-49). Such evidence that the accused products are used in arthroscopic surgery is not improper and, to the contrary, supports a finding that the accused products were specially designed to infringe.

2. The Evidence Was Conclusive That There Are No Substantial Noninfringing Uses Of The Accused Products.

Smith & Nephew's argument that there are substantial noninfringing uses for the accused devices fails because the evidence showed that the devices were designed to infringe and that any noninfringing use is occasional and inadvertent. *Preemption Devices v. 3M*, 630 F. Supp. 463, 471 n.10 (E.D. Pa. 1985), *aff'd in part*, 803 F.2d 1170 (Fed. Cir. 1986) ("occasional and aberrant use of these products, where they are clearly designed to be used in a system specified in the claims of a patent, does not rise to the level of 'a staple or commodity of commerce suitable for substantial noninfringing use'"). Smith & Nephew's only arguments as to substantial noninfringing uses, all of which lack merit, are directed to the "not in contact/spaced away" limitations of the '592 patent, the "vapor layer" limitation of the '882 patent, and the "electrosurgical system" limitation of the '536 patent.

With respect to the '592 patent, Smith & Nephew contends that use of the accused devices without the return electrode touching tissue is a substantial noninfringing use. (D.I. 459 at 21). For the Saphyre, there was substantial evidence that it was designed so that the return electrode would not contact tissue because the return electrode is spaced back from, and on a different plane than, the active electrode. (Tr. 397). There was also evidence that return electrode contact is not necessary for the Saphyre to work. (Tr. 555, 725). Moreover, all of the video clips shown at trial clearly demonstrated that there were many times when the return electrode was not in contact with tissue while the accused devices were being used. (PX 105, DTX 316, DTX 316, DTX 897). Smith & Nephew told its representatives to warn doctors in its

not to contact the return electrode with tissue. (PX 381, PX 390). This evidence was buttressed by a Smith & Nephew document entitled "Competitive Selling ArthroCare," which teaches doctors to hold the face of the active electrode of the Saphyre probe parallel with the tissue in order for the probe to ablate as intended. (PX 324 at ORA 65095). Based on the geometry and location of the active electrode, this demonstrates that the return electrode will not contact tissue when the probe is used as Smith & Nephew recommends.[8]

As for the ElectroBlade, Warren Heim testified that the return electrode was not intended to contact tissue when the device is in operation. (Tr. 581-82). In addition, the fact that the ElectroBlade is designed so that the return electrode is spaced proximally from the active electrode, and need not contact tissue for the device to work, shows that the return electrode was not intended to contact tissue. (Tr. 424, 727). Smith & Nephew's ElectroBlade IFU also warns doctors to keep the electrodes fully immersed in electrically conducting fluid, which supports the reasonable inference that Smith & Nephew instructed doctors not to contact tissue with the return electrode. (PX 189, PX 205). Moreover, Smith & Nephew instructs doctors to use the suction in the ElectroBlade to pull tissue into the active electrode blades and "present the smooth blade [active electrode] surface to the tissue," both of which mean that the return electrode is not in contact with tissue when the device is in use. (PX 199 at 7).

With respect to the Control RF, Mr. Heim admitted that the return electrode was not intended to contact the tissue. (Tr. 581-82, 957-58). The return electrode of the Control RF is also spaced back from, and on a different plane than, the active electrode, and thus is not in

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[8] Smith & Nephew takes the testimony of Dr. Goldberg out of context on this point. Smith & Nephew's quotes Dr. Goldberg as testifying that when the probes are in use, "as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently . . ." (D.I. 459 at 21). Smith & Nephew omits the rest of Dr. Goldberg's testimony, however, in which he stated "but often there isn't." (Tr. 423). As is clear, Dr. Goldberg was merely repeating what Mr. Marsden had said, and clarifying that often the return electrode is not in contact with the tissue when the probes are in use.

contact with the tissue. (Tr. 424) The evidence also showed that the return electrode of the Control RF need not contact tissue in order for the device to work. (Tr. 725).

From all of this evidence, the jury reasonably could conclude that use of the accused products with the return electrode in contact with the tissue is not a substantial non-infringing use.

Smith & Nephew's argument on the '882 patent, that a substantial noninfringing use of the Saphyre and Control RF probes is to use them for coagulation (as opposed ablation) and thus not form a "vapor layer," is baseless. (D.I. 459 at 21). As an initial matter, Smith & Nephew calls the probes "ablation" probes in its IFUs and Sales Guides. (PX 381, PX 390, PX 593 at 11). Moreover, the Sales Guides for both probes indicate that they are intended primarily for ablation, even though they also can provide coagulation. (PX 390 at 10; PX 593 at 29). The evidence also showed that Smith & Nephew markets the Saphyre and Control RF for use in the ablation, not coagulation, segment of the arthroscopy market. (PX 390 at 4, PX 593 at 5). As such, there is no basis on which to disturb the jury's finding that there are no substantial noninfringing uses for the Saphyre and Control RF that do not include a vapor layer.

As for the '536 patent, the evidence showed – contrary to Smith & Nephew's arguments – that using "the probes as part of an electrosurgical system that does not have a fluid supply as part of a 'unitary whole'" is not a substantial noninfringing use. (D.I. 459 at 21). All of the witnesses at trial agreed that the accused devices must be used with electrically conducting fluid. (Tr. 398, 405, 412, 848, 1013). Moreover, Dr. Goldberg, Ms. Drucker, and Mr. Sparks all testified that electrically conducting fluid must be delivered to the target site in arthroscopic surgery. (Tr. 483, 814, 1013-14). From this evidence, the jury was free to conclude that the use of the probes without an electrically conducting fluid supply is not a substantial noninfringing use.

G. There Was Substantial Evidence From Which A Reasonable Jury Could Conclude That Smith & Nephew Induces Infringement.

Both the design of the accused devices and Smith & Nephew's instructions to doctors about using them are strong evidence of inducement of infringement. As discussed above, the accused products are designed so that they need electrically conducting fluid to work. (Tr. 398, 405, 412, PX 189, PX 205). There also was substantial evidence that electrically conducting fluid must be delivered to the target site in order for a circuit to be completed between the active and return electrodes. (Tr. 398-99, 405, 412). Moreover, the accused products are designed so that the return electrode does not contact tissue due to the spacing and geometry of the electrodes, and the jury was shown video clips which bore this out. (PX, 105, DTX 315, DTX 316, DTX 897). The jury reasonably could conclude that the design of the accused devices induces doctors to infringe. (PX 197, PX 350, PX 462A, PX 510).

In addition, there was substantial evidence at trial that Smith & Nephew instructs and trains doctors to use the accused products in an infringing way. The IFUs for both the ElectroBlade and Control RF instruct doctors that the devices are contraindicated for procedures where electrically conducting fluid is not used. (PX 189, 732). The testimony was clear that these IFUs are included in the package of every accused device sold by Smith & Nephew. (Tr. 550-51, 565). Similarly, Smith & Nephew's Saphyre Sales Guide states that a conductive irrigation solution is "required" to be used with the Saphyre. (PX 390 at 11). Moreover, Smith & Nephew's Sales Guides, IFUs, Sales Training CD, and "Competitive Selling ArthroCare" document show that Smith & Nephew instructs doctors not to contact tissue with the return electrode. (PX 189, PX 199, PX 324, PX 381, PX 390, PX 593, PX 732).

Smith & Nephew's argument that ArthroCare presented evidence of copying which was "highly prejudicial" and an "*ad hominem* attack" is baseless. (D.I. 459 at 22-23). The evidence showed that Smith & Nephew engineers knew about and read ArthroCare's patents long before Smith & Nephew launched the infringing products. For example, Ms. Knudsen admitted that she

had read ArthroCare's patents before the Saphyre design was completed. (Tr. 991). The evidence showed that Mr. Heim had read and analyzed two of the three patents-in-suit before Smith & Nephew even began its design of the Control RF and ElectroBlade. (Tr. 936-37 and PX 735 at 23-24). There was also testimony that both Mr. Heim and Ms. Knudsen had evaluated ArthroCare's patented products in designing the infringing products. (Tr. 951 & 977-78). Such evidence is strong circumstantial evidence, which the jury was entitled to accept, that Smith & Nephew "knew or should have known that its encouragement and instruction would likely result in" doctors using the accused products to directly infringe, as required by the Court's jury instructions for a finding of inducement. (Tr. 1724).

II. SMITH & NEPHEW MAY NOT RAISE INVALIDITY IN A RULE 50(B) MOTION BECAUSE IT FAILED TO PRESERVE THE ISSUE.

Smith & Nephew's motion with respect to invalidity must be denied because it failed to preserve the issue under Rule 50(a) before the case was submitted to the jury. A Rule 50(a) motion must specifically set forth the grounds on which relief is sought, and the failure to do so renders a subsequent Rule 50(b) motion on any unidentified issue "constitutionally impermissible." *Duro-Last v. Custom Seal, Inc.*, 321 F.3d 1098, 1107 (Fed. Cir. 2003) (holding that a Rule 50(b) movant "waived its right to file a post-verdict JMOL motion on obviousness because its pre-verdict JMOL motion raised only the issues of inequitable conduct and the on-sale bar."); *Foster v. Nat'l Fuel Gas Co.*, 316 F.3d 424, 429 (3d Cir. 2003) ("The requirement that the *specific issue* be raised first in the motion for a directed verdict, before the issue is submitted to the jury, affords the non-moving party an opportunity to reopen its case and present additional evidence.") (emphasis added); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1187 (Fed. Cir. 2002) (reversing grant of JMOL where plaintiff moved on some invalidity issues before the case was submitted to the jury, but "did not make a motion for JMOL

on enablement before the case was submitted to the jury. As such, it was not entitled to move for JMOL on the issue after the verdict.").

Smith & Nephew never made a Rule 50(a) motion on invalidity. Smith & Nephew made an oral motion under Rule 50(a) at the close of ArthroCare's case. (Tr. 1161). This could not have been directed to the issue of validity, however, because validity was not a part of ArthroCare's case. Later in the trial, on May 9, 2003, Smith & Nephew "renewed its Rule 50 motion," but never expanded its motion to include validity. (Tr. 1549). On the same day, Smith & Nephew filed a written motion for judgment as a matter of law which was directed solely to issues of infringement. (D.I. 400 at 1 n.1). On May 12, 2003, counsel for Smith & Nephew said, "I believe I renewed our motion on Friday. To the extent I didn't, I renew it now before you charge the jury." (Tr. 1700). None of this constitutes a motion under Rule 50(a) on the issue of validity. As a result, Smith & Nephew's motion for JMOL on invalidity should be denied.

III. A REASONABLE JURY COULD CONCLUDE THAT SMITH & NEPHEW FAILED TO MEET ITS BURDEN OF PROVING INVALIDITY BY CLEAR AND CONVINCING EVIDENCE.

If, notwithstanding the foregoing, the Court decides to address Smith & Nephew's invalidity arguments, those arguments should be rejected in any event.

A. The Jury Was Free To Disregard The Unpersuasive Testimony Of Smith & Nephew's Expert Witnesses On Invalidity And Find That Smith & Nephew Failed To Meet Its Burden.

At the heart of Smith & Nephew's argument on invalidity is its legally incorrect contention that the jury had to accept the testimony of its expert witnesses on invalidity simply because the testimony was not contradicted by the testimony of an expert witness for ArthroCare. (D.I. 459 at 24). This, of course, is not the law. "Patent owners are never in law required to prove facts establishing validity." *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1511 (Fed. Cir. 1984). Where there is a verdict of validity, "the question is not whether the patentee

had introduced sufficiently substantial evidence to support the verdict, but whether the challenger's evidence so met the burden imposed by 35 U.S.C. § 282 that reasonable jurors could not have concluded that the challenger failed to overcome that burden." *Perkin-Elmer Corp. v. Computer Vision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984) (applying Third Circuit law). Thus, "a jury or a court may reach a conclusion that a patent remains valid *solely* on the failure of the patent challenger's evidence to convincingly establish the contrary." *Orthokinetics, Inc., v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986) ("A patent being presumed valid at birth, a patentee need submit *no* evidence in support of a conclusion of validity by a court or a jury.") (emphasis original).

In order to succeed on its anticipation defense, Smith & Nephew had to prove by clear and convincing evidence that every limitation of ArthroCare's asserted claims was contained either expressly or inherently in a single prior art reference. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001). Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will not be deemed to anticipate a subsequent claim unless the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002).

Smith & Nephew's clear and convincing burden was more difficult to meet in this case because all of the asserted references had been before the PTO during the original prosecution of the patents-in-suit or the '536 Reexamination. *BOC Healthcare, Inc. v. Nellcor, Inc.*, 892 F. Supp. 598, 602 (D. Del. 1995) (when the references at issue are the same references that were before the PTO, "the burden on the party asserting invalidity is more difficult to meet."); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc*, 796 F.2d 443, 447 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987). Thus, Smith & Nephew must show not only that no reasonable jury could find that it failed to meet its burden of showing invalidity by clear and convincing evidence,

Smith & Nephew must do so in light of the fact that its burden was "more difficult" to meet with respect to the references that had been cited to the PTO.

B. Smith & Nephew Failed To Show That The '536 Patent Was Anticipated.

1. The Jury's Verdict That The Pao '499 And Doss '007 Patents Do Not Anticipate Should Not Be Disturbed.

Both the Pao '499 patent and the Doss '007 patent were cited to the examiner during the prosecution of the '536 patent, and the examiner allowed the claims over them. (JTX 1). As a result, the jury's verdict must be viewed in light of the fact that Smith & Nephew's burden of proving anticipation by clear and convincing evidence was "more difficult" to meet. *BOC Healthcare, Inc.*, 892 F. Supp. at 602.

With respect to the Pao '499 patent, a reasonable jury could conclude that Smith & Nephew failed to show that it discloses a "current flow path" through electrically conducting fluid, as required to anticipate claims 46 and 56.[9] Dr. Taylor, the only Smith & Nephew witness to testify about the Pao '499 patent, agreed on cross-examination that it discloses not only placing both electrodes in contact with the tissue, but actually inserting the electrodes into the tissue. (Tr. 1409-12).[10] This is clear from the Pao '499 patent itself, which Dr. Taylor agreed teaches that "the end of the probe region is placed against the tissue causing the first ends of the axial and outer electrodes respectively to come into contact with the tissue." (Tr. 1407-8). Dr. Taylor also agreed that the Pao '499 patent discloses that electrical current "flows through the tissue between

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[9] The "current flow path" limitation appears in independent claim 45, from which claims 46 and 56 depend.

[10] Contrary to Smith & Nephew's assertion (D.I. 459 at 26), ArthroCare's cross examination of Dr. Taylor on the Pao '499 patent was directed to the "current flow path" limitation of claim 45, not the "return electrode being sufficiently spaced limitation" of claim 47. (Tr. 1408-12).

the axial and outer electrodes." (Tr. 1408). The jury was entitled to conclude from this evidence that the Pao '499 patent does not disclose the claimed current flow path through electrically conducting fluid.

As for the Doss '007 patent, Smith & Nephew failed to show that it discloses a "connector near the proximal end of the shaft," as required by the asserted claims of the '536 patent. In fact, Dr. Taylor admitted that there was no disclosure in the Doss '007 patent of the location of a connector at all. (Tr. 1400) (agreeing that "there is no specific mention of the location of" the connector). Despite this admission, Smith & Nephew makes the unsupported argument that "a wire that passes out of the proximal end" of the device disclosed in the Doss '007 patent "would be a connector." (D.I. 459 at 29). Even if there were testimony in the record to this effect, which there is not, this argument makes no sense because a wire is described as a conductor, not a connector, in the '536 patent. (JTX 1 at 10:49-57). Moreover, the mere presence of wire passing out of the proximal end of a device does not show a connector near the proximal end of the shaft. To the contrary, the wire could run from the tip of the device all the way to the power supply, thus rendering the phrase "near the proximal end of the shaft" meaningless.

Smith & Nephew also failed to show that the Doss '007 patent anticipates the '536 patent because there is no disclosure of a return electrode in that reference. ArthroCare's cross-examination of Dr. Taylor clearly established that both electrodes disclosed in the Doss '007 patent are active electrodes and that there is no return electrode. Dr. Taylor agreed that both electrodes are intended to cause a tissue effect. (Tr. 1396). Dr. Taylor also testified that the two electrodes work to form a "toroid," or donut-shaped, treatment region between the electrodes. (Tr. 1398-99). This testimony demonstrates that both electrodes are active, because under the Court's claim construction, an active electrode is "a stimulating electrode. . . applied to tissue for stimulation." (D.I. 353 at 3). In addition, Dr. Taylor was impeached at trial with his deposition testimony in which he agreed that all of the electrodes in each embodiment of the Doss '007

patent had substantially the same current density.[11] (Tr. 1385). Thus, the Doss '007 patent does not disclose a return electrode because the Court's claim construction requires a return electrode to have a "lower current density" than the active electrode.

2. The Jury's Verdict That Neither The Roos And Elsässer Article Nor The Roos '198 Patent (the "Roos References") Anticipates The '536 Patent Should Not Be Disturbed.

The jury's determination that Smith & Nephew failed to meet its burden of proving invalidity is substantially supported by the fact that the Roos references were disclosed to the PTO during the reexamination of the '536 patent. (Tr.1336-38, PX 7). A board of three examiners reviewed the patentability of the asserted claims of the '536 patent in light of the Roos references during the reexamination and concluded that they did not render any of the claims unpatentable. (Tr. 1337-38). The PTO issued a Notice of Intent to Issue Reexamination Certificate on March 14, 2003. (Tr. 1538-40). Thus, the jury's determination that Smith & Nephew failed to meet its burden as to the Roos references must be viewed in light of the fact that Smith & Nephew's burden in proving anticipation was "more difficult" to meet.

As with the Doss '007 patent, Smith & Nephew failed to show that there is a connector near the proximal end of the shafts of the devices disclosed in the Roos references that connects the electrode terminal to the generator, as required by claims 46, 47 and 56 of the '536 patent. Dr. Taylor admitted that there is no disclosure of the location of a connector anywhere in the Roos '198 patent. (Tr. 1371-72). As for the Roos and Elsässer article, Dr. Taylor identified no disclosure in the article which described the function of the structure at the proximal end of the device which he contended was a connector. (Tr. 1298). The jury was free to disregard his testimony as insufficient to show a connector for "electrically coupling the electrode terminal to

[11] Although Dr. Taylor tried to explain away his deposition testimony as a mistake, the jury was free to reject his trial testimony. (Tr. 1385-86).

the electrosurgical power supply," especially since Dr. Taylor had used the word "connector" to describe a structure that connected the device in the Pao '499 patent to a fluid supply. (Tr. 1311). In light of this lack of evidence of a connector, Smith & Nephew cites to several passages in the Roos references in a misguided attempt to show that a connector is inherent. The first passage Smith & Nephew quotes (D.I. 459 at 30) is from the '198 patent and discusses a cable leading to the return electrode, not a connector for electrically coupling the active electrode, as required by the asserted claims. The second passage Smith & Nephew cites, also from the '198 patent, discusses only an "insulated cable means," which is a conductor, not a connector, and in any event does not disclose its location with respect to the proximal end. (*Id.*) Finally, Smith & Nephew points to figure 9 in the Roos and Elsässer article as evidence of a connector. (D.I. 459 at 30). Figure 9, however, does not disclose what the structure at the proximal end actually does, such as whether it connects the active electrode, the return electrode, or a fluid supply, or has some other function altogether.

Dr. Taylor's testimony also did not establish that a connector near the proximal end of the shaft for coupling the electrode terminal to the generator is inherently disclosed in either of the Roos references. As Smith & Nephew points out, Dr. Taylor testified that "you do realize that all resectoscopes have connectors at the back of the resectoscope." (Tr. 1371). This testimony, however, was properly rejected by the jury because it lacked any basis, was conclusory, was not corroborated with any documents, and does not specify what the "connector" couples together. Similarly, Dr. Taylor's testimony that "there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope" (Tr. 1372) is insufficient because the mere fact that devices on the market today may have connectors does not establish (a) that the connector is one that connects the electrode terminal to the generator, or (b) that a connector is inherent in the Roos references that were published over 20 years ago. *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002) ("inherent anticipation requires that the missing

descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art").

Dr. Taylor's admissions also clearly establish that the Roos references do not disclose the use of an electrically conducting fluid. Dr. Taylor testified that the Roos references do not disclose the use of either saline or Ringer's lactate. (Tr. 1340-43, 1375). He also testified that the Roos references describe the use of prior art monopolar devices for TURP procedures, in addition to the bipolar devices Smith & Nephew alleges anticipate. (Tr. 1340-42, 1374-75). As Dr. Taylor testified, the liquid used in these prior art monopolar devices for TURP procedures was electrically non-conducting. (*Id.*). This is significant because Dr. Taylor conceded that the Roos references do not differentiate between the liquid used with the bipolar devices and the liquid used with the monopolar devices. (Tr. 1343-44 ("washing water" and "washing liquid"), 1376-77 ("irrigation liquid"), 1350-51). From this, the jury was free to conclude that the liquid described in the Roos references was not electrically conducting fluid.

In addition, Dr. Taylor's testimony as to Figure 5 of the Roos '198 patent establishes that the fluid it mentioned was not electrically conducting. Dr. Taylor agreed that if the liquid disclosed in Figure 5 of the Roos '198 patent were electrically conducting, there would be no need for the steel band described in Figure 5 to rest "on the tissue in large area form so that good electrical contact is ensured," as described in the '198 patent (Tr. 1345). Because Dr. Taylor testified that the same fluid is used for all of the embodiments of the '198 patent, there can be no doubt that the fluid disclosed in the '198 patent was not electrically conducting. (Tr. 1343-44, 1350-51, 1376-77).

Dr. Taylor's testimony concerning a later issued patent to Roos, the '667 patent, also shows that the fluid mentioned in the '198 patent was not electrically conducting. Specifically, Dr. Taylor agreed that if the fluid used in '198 patent had been an electrically conducting fluid, then the subsequent '667 patent would not have stated, as it did, that the device in the '198 patent did not work. (Tr. 1364-66). Moreover, Dr. Taylor conceded that if the device disclosed in the

'198 patent had used electrically conducting fluid, then the '667 patent would not have described the return electrode of the '198 patent as only being able to "enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process." (Tr. 1366). In light of Dr. Taylor's admissions, the jury was free to conclude that Smith & Nephew did not meet its burden of proving that the Roos '198 patent anticipated the asserted claims of the '536 patent.

Smith & Nephew makes much of the fact that claim 1 of the '198 patent refers to "liquid to provide electrical conductance."[12] (D.I. 459 at 32). This statement, however, begs the question rather than answering it. Dr. Taylor readily conceded that even non-conducting fluids will conduct electrical current. (Tr. 1373-75). This testimony is consistent with Figure 3 of the Roos and Elsässer article, which clearly shows current flux lines passing from the treatment electrode to the endoscope shaft through electrically non-conducting fluid. (*Id.*, DTX 594A). From this, the jury was free to conclude that simply because a fluid will conduct some amount of current does not make it an electrically conducting fluid, and thus that Smith & Nephew failed to show anticipation by clear and convincing evidence with the Roos references.

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[12] Smith & Nephew also cites to the Roos and Elsässer article, which states that "[the device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and offer such a low resistance that aberrant currents or leakage do not even occur." (D.I. 459 at 32). Smith & Nephew did not argue at trial that this portion of the Roos article discloses an electrically conducting fluid, nor could it have, because this portion of the article is not referring to the conductive qualities of the fluid. Instead, it is referring to the relatively lower resistance between the electrodes in the bipolar, as opposed to monopolar, configurations that results from the shorter distance between electrodes in a bipolar device (both electrodes are positioned close together in the vicinity of the surgical site) than in a monopolar device (the return electrode is positioned away from the surgical site outside the patient's body).

C. A Reasonable Jury Could Conclude That Smith & Nephew Failed To Meet Its Burden Of Proving That The '882 Patent Is Invalid.

1. The Manwaring '138 Patent Does Not Anticipate Claims 13 and 54 Of The '882 Patent.

The Manwaring '138 patent does not disclose the vaporization of electrically conducting fluid followed by electrical discharge, which is required by claims 13 and 54 of the '882 patent.[13] On cross examination, Dr. Manwaring admitted that his patent disclosed the opposite method: a spark discharge first, and then the vaporization of the fluid second. (Tr. 907-908). Smith & Nephew simply ignores this testimony, which undercut its anticipation defense.

Claim 13 of the '882 patent also requires the generation of photons having a wavelength in the ultraviolet ("UV") spectrum. The Manwaring '138 patent never mentions UV photons, and the jury was free to reject the conclusory testimony of Drs. Taylor and Manwaring that UV photons were inherently present in the device disclosed in the Manwaring '138 patent. Neither Dr. Taylor nor Dr. Manwaring performed any tests, analyzed any data, or offered any corroboration in scientific literature for their testimony. (Tr. 897-915, 1420-21, 1430).[14] As such, the jury was free to reject their testimony.

The Manwaring '138 patent also does not disclose evacuating fluid generated at the target site as required by claim 54. Instead, as Dr. Manwaring and Dr. Taylor both admitted, the Manwaring '138 patent only discloses drawing the fluid into the catheter tip where it remains in the vicinity of the tissue – not evacuating fluid beyond the vicinity of the target site. (Tr. 904-05, 1432-33). Contrary to Smith & Nephew's allegations, ArthroCare never argued that all of the

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[13] Asserted claims 13 and 54 depend from claim 1.

[14] Dr. Taylor testified that the presence of "a spark in an aqueous solution" would generate UV photons because that is "college chemistry." (Tr. 1420). Dr. Taylor, however, could produce no college chemistry textbook, or any other material, that supported this proposition.

fluid must be evacuated from the target site. (D.I. 459 at 40). Rather, ArthroCare pointed out, as the reference plainly shows, that the fluid is drawn into the device tip but is not removed from vicinity of the target site. This is not the claimed evacuation.

2. The Slager Reference Does Not Anticipate Any Asserted Claim Of The '882 Patent.

There was no evidence that the Slager reference discloses the application of energy to a "target site on a patient body structure," as required by claims 13, 17 and 54 of the '882 patent. Dr. Taylor agreed that the Slager reference discloses only the application of energy to a tissue sample in a lab dish, not to a patient body structure. (Tr. 1426-27). Significantly, Smith & Nephew argued both in its opening and closing arguments that it had not directly infringed the '882 patent because it had not performed "surgeries" on patients with the accused devices. (Tr. 190-91, 1651).[15] Thus, Smith & Nephew cannot argue that the disclosure of the application of energy to tissue samples in a lab dish anticipates claims requiring the application of energy to a target site on patient's body. It is axiomatic that, for a method claim, "that which infringes if later anticipates if earlier." *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1309 (Fed. Cir. 2002).

The fact that Mr. Eggers may have reduced the inventions to practice on tissue samples in bowls of saline is of no significance to whether Smith & Nephew met its burden. To the contrary, the purpose and efficacy of some inventions are "so obvious that their complete construction is sufficient to demonstrate workability, even though it does not perform all of the claim limitations." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1575, 1578 (Fed. Cir. 1996) (finding that testing in inventor's kitchen sink of an invention that ultimately included a claim limitation of preventing "traumatizing or becoming caught in the walls of a vessel into which the catheter is

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[15] In light of this argument, Smith & Nephew cannot be heard to argue now, as it does, that the preamble "does not constitute a claim limitation." (D.I. 459 at 37).

inserted" was sufficient actual reduction to practice, even though all of the limitations ultimately claimed were not met during the testing). Thus, the circumstances of Mr. Egger's reduction to practice do not change the fact that the Slager reference cannot anticipate because it does not disclose the application of energy to a "patient body."

As with the Manwaring '138 patent, the jury was entitled to find that Smith & Nephew failed to show that the UV photon limitation of claim 13 of the '882 patent is met by the Slager reference. Smith & Nephew relied exclusively on the cursory testimony of its expert, which the jury was entitled to disregard. (Tr. 1319). As such, the jury's verdict that the Slager reference does not anticipate must stand.

Smith & Nephew also failed to show that the Slager reference meets the limitations of claim 54, which require "a suction lumen having a distal end adjacent the electrode terminal." Dr. Taylor readily admitted that the Slager reference fails to disclose the location of a suction lumen. (Tr. 1425-26). From this, the jury reasonably could conclude that Smith & Nephew failed to show that the Slager reference anticipates claim 54 of the '882 patent.

3. The Jury Was Entitled To Conclude That Smith & Nephew Had Not Met Its Burden On Enablement.

To show enablement, Smith & Nephew was required to prove that one skilled in the art would not be able to make and use the claimed invention without undue experimentation. *Genetech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). As with anticipation, Smith & Nephew bore the burden of showing lack of enablement by clear and convincing evidence. *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

Smith & Nephew's total evidence in support of its enablement defense is the following testimony from Dr. Taylor:

> Q. Do you have any other basis for believing that the claims of the '882 patent are invalid?
>
> A. I am sorry, I am blanking on this.

Q. Sure.

A. When you say other opinions, do you mean other facts?

Q. Do you understand that ArthroCare contends that what is taught in the '882 patent is a new phenomenon?

A. I see what you mean. No, it is not a new phenomenon. It's been anticipated, it's been described in the prior art.

Q. If, in fact, it is a new phenomenon, do you believe there is an additional basis for the '882 patent to be found invalid?

A. Yes. One of the concerns I have – I think I expressed this yesterday – is that if the '882 patent is found to be invalid, then a large number of the devices that I have developed and, for that matter, a large number of the devices that have been developed in electrosurgery will infringe, because of the fact that what they are claiming is extremely broad.

Q. Does the '882 patent teach anything about how to achieve a new phenomenon that is different than the principle of operation of conventional electrosurgical devices?

A. No, it doesn't. I was perplexed and, frankly, am still perplexed about the overall phenomenon of Coblation.

Q. And is that defense also sometimes called nonenablement?

A. Yes, it is.

Q. Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A. Yes, I have an opinion.

Q. What is that opinion?

A. That it is not.

Q. Thank you.

(Tr. 1323-25). The jury was entitled to reject this testimony. Dr. Taylor obviously was led to his opinion by counsel after "blanking on this," and provided no basis for it in any event. Moreover, there was no basis for Smith & Nephew's expert to equate "Coblation" with the claims of the '882 patent. The rejection of this testimony as utterly lacking in credibility falls squarely within the prerogative of the jury.

In addition, the Court instructed the jury that in determining enablement it must consider whether "undue experimentation" is required. (Tr. 1731). Smith & Nephew, however, presented no evidence whatsoever that one of ordinary skill in the art would require undue experimentation to make and use the invention.

The table on page 43 of Smith & Nephew's brief proves nothing, since it omits several critical elements disclosed in the specification of the '882 patent, such as voltage, power, distance between the active and the return, fluid density, and the presence of asperities on the electrodes. (JTX 2). Smith & Nephew's enablement argument also fails because Dr. Taylor testified that one of skill in the art would follow the preferred teachings in the specification, and there is no evidence that one following the preferred teaching would not have been able to make and use the inventions without undue experimentation. (Tr. 1434-38).

D. A Reasonable Jury Could Conclude That Smith & Nephew Failed To Meet Its Burden Of Proving That The '592 Patent Is Invalid.

The Doss '007 patent, discussed above with respect to the '536 patent, does not disclose a return electrode. As such, it does not anticipate any of the asserted claims of the '592 patent. Moreover, the Doss '007 patent does not disclose a voltage in the range of 500 to 1,400 volts peak-to-peak as required by claims 21 and 42 of the '592 patent, but only 20 to 200 volts RMS (root-mean-square). As Dr. Taylor conceded, the Doss '007 patent does not disclose the waveform of the voltage, and if the waveform were square, then the peak-to-peak voltage in Doss '007 patent would be only 400, and not within the required range of 500 to 1,400. (Tr. 1402-04). Dr. Taylor simply presumed that the Doss '007 patent refers to a sine wave. *Id.* There was no basis for such a presumption. Indeed, the Slager reference relied on by Smith & Nephew discloses a *square* wave generator. (DTX 65 at SN11303). Dr. Taylor's assertion of a lack of awareness of a "commercially available square wave generator" does not establish the inherency of a sine wave in the Doss '007 patent. To the contrary, no matter what may have been

"commercially available," the disclosure of a square wave generator in the Slager reference proves that the waveform in the Doss '007 patent was not necessarily a sine wave. As such, the Doss '007 Patent does not anticipate the asserted claims of the '592 patent.

The Slager reference also does not anticipate the asserted claims of the '592 patent. As an initial matter, there is no disclosure of the application of energy to a body structure of a patient, which is required by all of the asserted claims. Moreover, the Slager reference does not disclose the location of the return electrode, and thus does not disclose the "not in contact/spaced away" limitations of the asserted claims of the '592 patent. Dr. Taylor testified that he could not determine the location of the return electrode in the Slager reference. (Tr. 1414-18). Thus, the jury was free to conclude, as it did, that the Slager reference did not meet the "not in contact/spaced away" limitations of the '592 patent by clear and convincing evidence.

CONCLUSION

For the reasons set forth herein, Smith & Nephew's Rule 50(b) motion for judgment as a matter of law should be denied in its entirety.

MORRIS, NICHOLS, ARSHT & TUNNELL

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
James W. Parrett, Jr. (#4292)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
Attorneys for Plaintiff ArthroCare Corporation

OF COUNSEL:

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
Silicon Valley Office
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

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